5. 510(k) Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of SDMA 1990 and 21 CFR 807.92.

Date prepared: November 24th 2011

The assigned 510(k) number is: _____

5-1. Applicant:

Fournitures Hospitalières industrie
6 Rue Nobel, Z.I. de Kernévez
29000 QUIMPER - FRANCE
Tel: (+33) 2.98.55.68.95
Fax: (+33) 2.98.53.42.13

5-2. Company Contact: Franck HUNT, General Manager
Tel: (+33) 2.98.55.68.95

5-3. Product :

Trade name: **CoLS® PEEK**

Common name: Fixation screw

Classification: Fixation screw:
Product code: HWC : screw, fixation, bone
Regulation: 21 CFR 888.3040
Class: II

5-4. Predicate/ Legally Marketed Devices :

Information on devices to which substantial equivalence is claimed:

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	TLS Fixation System
510 (K):	K080974
Manufacturer:	Smith & Nephew, Inc.
Device Trade Name:	BIOSURE® SYNC Smith & Nephew PEEK Interference Screws
510 (K):	K083226

K113591

5-5. Device Description:

The CoLS® PEEK is a screw made out of PEEK (Poly-Ether-Ether-Ketone) and used with the tape of TLS® fixation system agreed by FDA K080974.
To standardize CoLS® range, the TLS® tape will be called CoLS® tape.

The difference between CoLS® screw made out of PEEK and TLS® screw made out of titanium is only the raw material.

The CoLS® PEEK is intended to be implanted using the dedicated instrumentation supplied by the manufacturer.

5-6. Indications for Use/ Intended Use:

As stated in the Indications for Use section and on the product related labeling (instructions for use and commercial documents):

The **CoLS® PEEK** is designed for the fixation of tendons graft to the femur and tibia during orthopedic surgical procedures for Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) reconstructions.

5-7. Comparison of Technological Characteristics:

The CoLS® PEEK and the above selected predicate devices have the same intended use and substantial similar indications for use and share the following similarities:
- they are made out of the same material: PEEK,
- they are available in similar ranges of sizes,

5-8. Performances:

The CoLS® PEEK was tested according to ASTM F543-07. The test performed in ASTM F543 was the insertion torque test. After the testing was completed, it was determined that the CoLS® PEEK performances were substantially equivalent to those of the selected predicate devices.

Risks to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

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5-9. Conclusion:

Following the examination of all the above mentioned information, we believe that the CoLS® PEEK is substantially equivalent to the selected predicate devices in terms of material, ranges of sizes, intended use, performances, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Fournitures Hospitalières Industrie
% Mr. Franck Hunt
General Manager
6 Rue Nobel, Z.I. de Kernèvez
29000 Quimper
France

DEC 2 2 2011

Re: K113591
Trade/Device Name: CoLS® PEEK
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 24, 2011
Received: December 5, 2011

Dear Mr. Hunt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

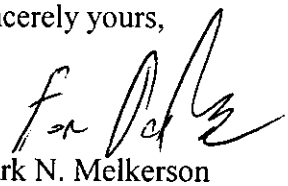
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K113591

Device Name:

CoLS® PEEK
This device is composed of fixation screw made out of PEEK.

Indications for Use:

The **CoLS® PEEK** is designed for the fixation of tendons graft to the femur and tibia during orthopedic surgical procedures for Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) reconstructions.

Prescription Use: __**Yes**__ AND/OR Over the counter Use: ___**No**____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113591